UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/368,378	01/14/95	BOVA D	94247

15M1/1122

REESE TAYLOR
RENNER KENNER GRIEVE BOBAK TAYLOR
AND WEBER
FIRST NATIONAL BANK SIXTEENTH FLOOR
AKRON OH 44308-1456

EXAMINER	
VENKAT, J	
ART UNIT	PAPER NUMBER
1502	16

DATE MAILED: 11/22/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

SUSPENSION OF ACTION , POSSIBLE INTERFERENCE

Claims 1-9, and 13-14 are allowable . Claims 13-14 can be allowed on a separate patent . Claims 1-9 interfere with O'NEIL PATENT No. 5 ,268 ,181 . Due to the potential interference , ex parte prosecution is SUSPENDED FOR A PERIOD OF 6 MONTHS from date of this letter . Upon expiration of the period of suspension , applicant should make an inquiry as to the status of the application .

J. Venkat

JYOTHSNA VENKAT
PRIMARY EXAMINER
GROUP 1500

O'Neill Patent Claims

1. A therapeutic method for lowering serum lipids or lipid components consisting essentially of administering to a human in need of such treatment an amount of a single daily dose of niacin which is effective to lower the nocturnal levels of a serum lipid or lipid component selected from the group consisting of total serum cholesterol, total triglycerides, lipoprotein a and low-density lipoprotein-cholesterol (LDL-C), wherein said dose of niacin is administered by ingestion of at least one controlled release tablet comprising, in admixture, about 5-30 % high viscosity hydroxypropyl methylcellulose having a nominal viscosity, 2% aqueous solution, of at least about 10,000 cps, a methoxyl content of about 7-30% and a hydroxypropyl content of about 7-20%, about 2-15% of a water-soluble pharmaceutical binder, about 2-20% of a hydrophobic component and about 30-90% niacin.

2. The method of claim 1 wherein said treatment also raises the levels of high density lipoprotein cholesterol (HDL-C).

3. The method of claim 1 wherein the single dose of niacin is administered with the evening meal of said human or after the evening meal of said human but before bedtime.

4. The method of claim 1 wherein the tablet further comprises a coating comprising a water-swellable polymer.

5. The method of claim 4 wherein the coating of the water-swellable polymer is overcoated with an enteric coating.

6. The method of claim 1 wherein the tablet comprises about 50-85% niacin.

7. The method of claim 1 wherein the hydrophobic component comprises a wax.

8. The method of claim 1 wherein the hydroxypropyl methyl cellulose has a nominal viscosity, 2 percent aqueous solution, of about 50,000-100,000 cps.

9. The method of claim 8 wherein the hydroxypropylmethyl cellulose has a nominal viscosity, two percent solution, of about 100,000 cps, a methoxyl content of about 19-24%, a hydroxypropyl content of about 7-12 percent, and a particle size where at least ninety percent passes through a USS 100 mesh screen.

10. The method of claim 1 wherein the water-soluble pharmaceutical binder is selected form the group consisting low-viscosity hydroxypropyl methylcellulose which has a nominal viscosity, two percent solution, of less than about 100 cps, polyvinyl pyrollidone, methyl cellulose, gelatin, starch, sucrose and lactose.

11. The method of claim 1 wherein the tablet is a 250 mg tablet, a 500 mg tablet, a 750 mg tablet or mixtures thereof.